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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,549	10/18/2004	Takahide Ohishi	Q102803	9316

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EXAMINER	
HOBBS, LISA JOE	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
04/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,549	OHISHI ET AL.	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10,13,15 and 17* is/are pending in the application.

4a) Of the above claim(s) *8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 13, 15, 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03 March 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 March 2008 has been entered.

Election/Restrictions

Claims 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 March 2007.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03 March 2008, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Status

Claims 7-10, 13, 15 and 17 are active in the case. Claims 1-6, 11-12, 14 and 16 have been cancelled by amendment. Claims 7, 13, 15 and 17 are under examination; claims 8-10 are withdrawn as drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 13, 15, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 21-25 of copending Application No. 10/975367. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method using a nucleotide vector comprising the same sequences; instant SEQ ID NO: 2 is identical to SEQ ID NO: 2 of 10/975367 and instant SEQ ID NO: 4 is identical to SEQ ID NO: 16 of 10/975367. The claims are directed to using identical polypeptides expressed from DNA vectors transfected into cells in method increasing insulin production, insulin content, and insulin-stimulatory signaling in the cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments filed 03 March 2008, with respect to the rejection of claim 7, as amended, under 35 USC 112, first paragraph, have been fully considered and are persuasive. The rejection of claims 7 and 13 is withdrawn based on the amendments to claim 7, removing the language allowing multiple, unspecified insertions, substitutions and deletions, and the multiple alignments presented. In the response, applicants note that sequences from more than one species have been presented, which species have significant identity and structural similarity; one of skill in the art would be able to determine the amino acids most likely to be essential to the structure and function of SEQ ID NOs: 2 and 4 and be able to make up to changes in 5% of the sequence while maintaining the stated activity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7, with dependent claim 13, recites the word "homology" in describing a relationship between SEQ ID NOs. Homology is an art term that connotes a qualitative relationship, frequently having some evolutionary component and does not definitively describe the metes and bounds of the claimed invention. Identity, however, is a quantitative relationship that can be mathematically calculated. For the purposes of this action, claim 7 has been interpreted to read (in part):

"(c) a polypeptide consisting of an amino acid sequence having 95% or greater identity with that of SEQ ID NO: 2 or 4, and exhibiting an activity of promoting insulin production by activation".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 13, 15 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 7,108,991, issued 19 September 2006, which claims priority to provisional application 60/141,448, filed 29 June 1999).

Chen et al teach a method of using a G protein-coupled receptor called RUP3 in an assay for identifying compounds that modulate insulin production. RUP3 (also identified in the patent of Chen et al as SEQ ID NO: 8) is identical to instant SEQ ID NO: 2. Specifically, the RUP3 DNA is inserted into a DNA vector which is transfected into cells; the cells are then contacted with an agonist or antagonist that inhibits or stimulates insulin production (see Claims 1-11, for example). The step of "confirming" recited in instant claim 13 is a step of repeating; one would expect the same results from the steps recited in Chen et al regardless of the number of times the assay is performed. Therefore the teachings of Chen et al are deemed to anticipate instant claims 7 and 13-17.

Response to Arguments

Applicant's arguments filed 03 March 2008 have been fully considered but they are not persuasive. Applicants argue that Chen et al. do not fully recognize the functionalities of the RUP3 protein and its relationship to insulin, particularly that Chen et al. do not disclose that RUP3 promotes insulin increase merely disclosing that RUP3 plays a role in insulin "regulation". However, "regulation" could be either increasing or decreasing the amount of the compound of interest, thus "regulation" clearly encompasses increasing insulin. Applicants also argue that the date on the Chen et al. disclosure does not antedate the instant disclosure since the claims precisely stating the precise language of the method steps was added by preliminary amendment. However, the filing date of the disclosure of the Chen et al. application, which has been accorded the provisional filing date, is prior to the earliest filing date of the instant application and the Chen et al. provisional application states (at pages 14 and 19, for example) that the RUP3 protein can be used to screen candidate compounds and provide for the direct identification of candidate compounds, agonists, inverse agonists, and partial agonists, which act at this cell surface protein

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh